

**6178. Conjugated estrogen powder and conjugated estrogen granules.** (F.D.C. No. 43915. S. Nos. 65-949/50 P, 65-960 P.)

**QUANTITY:** 2 cans, 500 grams each, and 3 cans, 2 kilograms each, of estrogen powder, and 7 cans of estrogen granules, at Buffalo, N.Y.

**SHIPPED:** Between July 1954 and 8-5-59, from Montreal, Canada, by Steroid Laboratories, Ltd.

**LABEL IN PART:** (Can) "Product of Steroid Laboratories Limited \* \* \* Montreal, Canada, 500 Grams [or "2 Kilograms"] Conjugated Estrogens (Equine) Powder \* \* \* Control No. 71302 [or "73730"]" or "1546 Grams Conjugated Estrogens (Equine) Granules. 5.67 mg/gram \* \* \* Control No. 87243."

**RESULTS OF INVESTIGATION:** Analysis showed that the total estrogen content corresponded to not more than (2 cans) 12.6 mgs., (3 cans) 11.2 mgs., and (7 cans) 4.7 mgs. of estrone per gram.

**LIBELED:** 11-17-59, W. Dist. N.Y.

**CHARGE:** 501(c)—when shipped and while held for sale, the strength of the article differed from that which it purported and was represented to possess; and 502(a)—the label statements of the articles (2 cans) "15.45 mgm/gm," (3 cans) "13.29 mgm/gm," and (7 cans) "5.67 mg/gram" were false and misleading.

**DISPOSITION:** 2-8-60. Consent—claimed by Steroid Laboratories, Ltd., Montreal, Canada; one can was destroyed and the remainder were relabeled.

**6179. Vernalin (ophthalmic solution).** (F.D.C. No. 43970. S. No. 69-722 P.)

**QUANTITY:** 70 8-oz. cartoned btls. at Trenton, N.J.

**SHIPPED:** 10-27-59, from Philadelphia, Pa., by Wall & Ochs, Inc.

**LABEL IN PART:** (Btl. & ctn.) "Vernalin (Improved) Contains: Sodium Carbonate Monohydrated (Active Ingredient) Camphor Water, Rose Water, Fluorescein Sodium (Diagnostic Agent) Chlorbutanol 0.5% as preservative \* \* \* Wall & Ochs \* \* \* Chestnut Street, Phila."

**ACCOMPANYING LABELING:** Circular entitled "Vernalin."

**RESULTS OF INVESTIGATION:** Examination showed that the article was contaminated with viable microorganisms.

**LIBELED:** 12-17-59, Dist. N.J.

**CHARGE:** 501(c)—when shipped, the quality and purity of the article fell below that which it purported to possess; and 502(a)—the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for all types of conjunctivitis.

**DISPOSITION:** 1-18-60. Default—destruction.

**6180. Digitalis tablets.** (F.D.C. No. 43926. S. Nos. 85-337/8 P.)

**QUANTITY:** 160,000 tablets in bulk drums and 48 1,000-tablet btls. at Edgewater, N.J.

**SHIPPED:** During May 1959, from New York, N.Y., by Excel Pharmacal Co.

**LABEL IN PART:** (Drum) "Tablets Digitalis Grains 1½ gr." and (btl.) "Excel 1,000 Tablets Digitalis 1½ Grains \* \* \* USP \* \* \* Manufactured by Excel Pharmacal Company, New York, N.Y."

**RESULTS OF INVESTIGATION:** Analysis showed that the digitalis potency of the article was less than the declared potency of 1½ grains per tablet. The tablets in the bottles had been repackaged by the dealer from the bulk drums shipped as described above.

**LIBELED:** 11-24-59, Dist. N.J.

**CHARGE:** 501(b)—when shipped, the strength of the article fell below the standard for digitalis tablets set forth in the United States Pharmacopeia; and 502(a)—the label statement "Digitalis 1½ Grains" was false and misleading.

**DISPOSITION:** 1-11-60. Default—destruction.

**6181. Canfield liquid lubricating jelly.** (F.D.C. No. 44043. S. No. 98-069 P.)

**QUANTITY:** 24 cases, each containing 12 16-oz. jars, at St. Louis, Mo.

**SHIPPED:** 10-12-59 and 11-18-59, from Minneapolis, Minn., by C. R. Canfield & Co.

**LABEL IN PART:** (Case) "No. 1921 Canfield Original Liquid Lubricating Jelly \* \* \* Sterile \* \* \* Ipse-Sterilis \* \* \* C. R. Canfield & Co. 2736-38 Lyndale Avenue, South, Minneapolis 8, Minnesota \* \* \* Control Number 4349."

**RESULTS OF INVESTIGATION:** Examination showed the article was contaminated with viable microorganisms.

**LIBELED:** 1-27-60, E. Dist. Mo.

**CHARGE:** 501(c)—when shipped, the quality and purity of the article fell below that which it purported and was represented to possess; and 502(a)—the label statement "Original Liquid Lubricating Jelly \* \* \* Sterile \* \* \* Ipse-Sterilis" was false and misleading as applied to an article that was not sterile.

**DISPOSITION:** 3-28-60. Default—destruction.

**6182. Prophylactics.** (F.D.C. No. 44356. S. No. 85-083 P.)

**QUANTITY:** 9 ctns., 50 gross boxes each, at Baltimore, Md.

**SHIPPED:** During the week of 2-1-60, from Hartville, Ohio, by Allied Latex Sales Co.

**LABEL IN PART:** "Liquid latex, sold for prevention of disease only, made in U.S.A., C-1-60A."

**RESULTS OF INVESTIGATION:** Examination showed that 1.5 percent of the article was defective in that it contained holes.

**LIBELED:** 2-26-60, Dist. Md.; amended 3-29-60.

**CHARGE:** 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "sold for prevention of disease only" was false and misleading as applied to an article containing holes.

**DISPOSITION:** 5-10-60. Default—destruction.

#### DRUG FOR VETERINARY USE

**6183. Wirthmore Coccidiosis Treatment.** (F.D.C. No. 44260. S. No. 91-065 P.)

**QUANTITY:** 20 100-lb. bags at Plainfield, Conn.

**SHIPPED:** 12-8-59, from Bridgewater, Mass., by Eastern Grain Co.

**LABEL IN PART:** (Bag) "Wirthmore Coccidiosis Treatment Ration 411 \* \* \* Active Drug Ingredient Sulfaquinoxaline .05% \* \* \* Manufactured for Wirthmore Feeds, Inc., Waltham, Mass."

**RESULTS OF INVESTIGATION:** Examination showed that the article contained approximately 0.027 percent of sulfaquinoxaline.

**LIBELED:** 3-4-60, Dist. Conn.